IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LARRY G. JUNKER : CIVIL ACTION

:

Plaintiff,

v. : No. 13-4606

:

MEDICAL COMPONENTS, INC., et al.

:

Defendants.

v

Goldberg, J. January 4, 2019

MEMORANDUM OPINION

This is an action for infringement of a design patent. Plaintiff, Larry Junker, is the owner of U.S. Design Patent Number D450,839, entitled "Handle for Introducer Sheath" (the "D'839 Patent"). Plaintiff contends that Defendants, Medical Components, Inc. and Martech Medical Products, Inc., have violated 35 U.S.C. § 271, *et seq.*, by selling medical devices embodying Plaintiff's patented design. Defendants allege non-infringement and that the D'839 Patent is invalid.

Currently before me are the parties' cross-motions for summary judgment and <u>Daubert</u> motions. Both parties seek summary judgment on the infringement issue, as well as on certain invalidity defenses asserted by Defendants. For the reasons set out below, I conclude that there are disputed issues of material fact that preclude summary judgment in favor of either party on infringement, as well as on several asserted grounds of invalidity. As to those invalidity defenses for which there are no material facts in dispute, I conclude that Defendants have not, as a matter of law, met their burden of proving invalidity by clear and convincing evidence such that

summary judgment is warranted. In short, most of the issues raised in these motions will have to be resolved through a trial.

I. <u>FACTUAL & PROCEDURAL BACKGROUND</u>

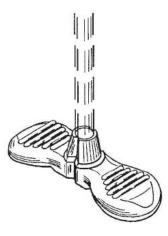
Many of the facts in this case are disputed, particularly those surrounding who invented the patented design. While the disputed facts are discussed in detail in Part III below, the following general facts are undisputed unless otherwise noted.

In August 1998, Plaintiff met with James Eddings, the owner of Galt Medical Corporation ("Galt Medical"), to discuss the development and marketing of an "introducer sheath," used in the medical insertion of catheters. Before this meeting, Plaintiff and Eddings executed a non-disclosure agreement. Shortly thereafter, in September 1998, Eddings founded a new company, Xentek Medical Inc. ("Xentek Medical"). (Pl.'s SOF ¶ 2; Defs.' SOF ¶ 2; Decl. of Larry G. Junker (hereinafter "Junker Decl.") ¶ 6; Dep. of James Eddings (hereinafter "Eddings Dep.") at 97:24-100:13; Decl. of James R. Eddings (hereinafter "Eddings Decl.") ¶ 2.)

In November 1998, Plaintiff met with Eddings and one of Eddings' associates, Richard Gillespie, to further discuss the development of an introducer sheath. Then, in December 1998, Plaintiff sent Eddings a fax about the design, noting that he "would really like to see longer (wider) handles," and providing a sketch. Thereafter, Gillespie provided Plaintiff with drawings of a design. (Pl.'s SOF ¶¶ 6, 8, 10; Defs.' SOF ¶¶ 6, 8, 10; Decl. of Richard Gillespie (hereinafter "Gillespie Decl.") ¶ 6.)

On February 7, 2000, Plaintiff applied to the U.S. Patent and Trademark Office ("PTO") for a design patent. On November 20, 2001, the PTO granted the application, issuing the patent at issue in this case, the D'839 Patent. The D'839 Patent lists Plaintiff as the sole inventor. (Pl.'s SOF ¶ 12; Defs.' SOF ¶ 12; Decl. of James D. Petruzzi ("Petruzzi Decl."), Ex. 15 at 1.)

The D'839 Patent contains a single claim: "The ornamental design for a handle for introducer sheath, as shown and described." Included with the D'839 Patent are nine figures, which show the introducer sheath from different perspectives, including from the front, the side, above, and a cross-sectional view. Figure 1, shown below, is displayed on the first page of the D'839 Patent, and is illustrative of the overall design.



The introducer is shown in solid lines. Broken lines illustrate the sheath itself, which is not part of the claimed design. The introducer has two Mickey Mouse ear shaped handles, referred to as "wings," which are connected in the center by a cone-shaped "hub," into which the sheath is inserted.

In January 2003, Plaintiff brought suit in the United States District Court for the Northern District of Texas, alleging that Eddings, Galt Medical, and Xentek Medical infringed the D'839 Patent. (This lawsuit is referred to hereinafter as "the Eddings Suit.") Following a jury trial, the court entered judgment in favor of Plaintiff and against the Eddings Suit defendants. See Junker v. Eddings, No. 3:02-cv-0172, 2004 WL 5552032 (N.D. Tex. Jan. 16, 2004). The jury concluded that the D'839 Patent was not invalid, and that the Eddings Suit defendants willfully infringed it. On appeal, the United States Court of Appeals for the Federal Circuit affirmed as to these issues.

See Junker v. Eddings, 396 F.3d 1359 (Fed. Cir. 2005). Following the conclusion of the Eddings Suit, the PTO re-examined the D'839 Patent and upheld its validity. (Pl.'s SOF ¶ 29, Defs.' SOF ¶ 29.)

Plaintiff brought this action on August 8, 2013, alleging that Defendants have made or sold four products that infringe the D'839 Patent. (These four products are referred to hereinafter as "the Accused Products"). The Accused Products are shown below, alongside the corresponding figures of the D'839 Patent:



¹ The Federal Circuit reversed on the issue of attorneys' fees, which is not relevant to the issues in this case

² As Defendants note, the Super Sheath and Super Sheath 2.0 are the same design, differing only in the material out of which the "dilator tube," which is not part of the D'839 Patent's design, is made. (See Defs.' Mem. in Supp. 25.)

Defendants answered and counterclaimed, contending that the D'839 Patent is invalid on various grounds, and that the Accused Products do not infringe. Following discovery, this matter proceeded to claim construction, where I construed the single claim of the D'839 Patent as follows:

The D'839 Patent claims the ornamental design of a handle for an introducer sheath, as shown in Figures 1–9. The broken lines in the Figures of the D'839 Patent represent unclaimed subject matter.

(Claim Construction Or., Doc. No. 192.) In reaching this construction, I rejected Defendants' proposal to set out a more detailed written description of the design. I also rejected Plaintiff's argument that the hub is functional and thus not part of the claimed design. Rather, I concluded that the hub contributes to the ornamentation of the overall design and is thus part of the claim.

Now, following claim construction, both parties have filed cross-motions for summary judgment. Both Plaintiff and Defendants contend that summary judgment in their favor on the issue of infringement is warranted. Plaintiff also moves for summary judgment on several of Defendants' asserted invalidity defenses, arguing that these defenses fail as a matter of law because Defendants have not met their burden of establishing them by clear and convincing evidence. Defendants, in turn, assert that summary judgment is appropriate on several grounds of invalidity, contending that no genuine dispute of material fact exists as to these defenses. Finally, Plaintiff contends that he is entitled to summary judgment on the issue of damages.

For the reasons that follow, I conclude that there are material facts in dispute that preclude summary judgment in favor of either party on infringement, as well as on several of the asserted grounds of invalidity. As to those invalidity defenses for which there are no material facts in dispute, I conclude that Defendants have not met their burden of proving invalidity by clear and convincing evidence.

II. <u>LEGAL STANDARD FOR SUMMARY JUDGMENT</u>

Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A party moving for summary judgment bears the initial burden of demonstrating that there are no genuine issues of material fact in dispute, and that judgment is appropriate as a matter of law. <u>Id.</u>; <u>Celotex Corp. v. Catrett</u>, 477 U.S. 317, 323 (1986). However, once a properly supported motion for summary judgment has been made, the burden shifts to the non-moving party, who must set forth specific facts showing that there is a genuine issue of material fact for trial. <u>Anderson v. Liberty Lobby, Inc.</u>, 477 U.S. 242, 250 (1986).

An issue is "genuine" if a reasonable jury could rule in favor of the non-moving party based on the evidence presented. Kaucher v. Cnty. of Bucks, 455 F.3d 418, 423 (3d Cir. 2006). A factual dispute is "material" if it might affect the outcome of the suit under the appropriate governing law. Id. at 423. The non-moving party cannot avert summary judgment with speculation or conclusory allegations, but rather must cite to the record. Ridgewood Bd. of Educ. v. N.E. for M.E., 172 F.3d 238, 252 (3d Cir. 1999); Fed. R. Civ. P. 56(c). On a motion for summary judgment, the court considers the evidence in the light most favorable to the non-moving party. Anderson, 477 U.S. at 256.

"The rule is no different where there are cross-motions for summary judgment," because such cross-motions are "no more than a claim by each side that it alone is entitled to summary judgment, and the making of such inherently contradictory claims does not constitute an agreement that if one is rejected the other is necessarily justified or that the losing party waives judicial consideration and determination whether genuine issues of material fact exist."

<u>Lawrence v. City of Phila., Pa.</u>, 527 F.3d 299, 310 (3d Cir. 2008) (internal quotation marks

omitted). Accordingly, while I will discuss together the overlapping issues raised by the parties' cross-motions for summary judgment, I will bear in mind each party's burden on summary judgment.

III. DISCUSSION OF CROSS-MOTIONS FOR SUMMARY JUDGMENT

A. Infringement

Plaintiff contends that he is entitled to summary judgment as to each of the Accused Products on the issue of infringement, because they all "appear substantially the same as [his] design." (Pl.'s Mem. in Supp. 4.) Defendants respond that the Accused Products are so different from the design embodied by the D'839 Patent that "the ordinary observer would never be deceived into thinking that" the designs were the same, and thus I should deny Plaintiff summary judgment and instead grant summary judgment in their favor. (Defs.' Mem. in Supp. 25.) I disagree with both Plaintiff and Defendants, and conclude that summary judgment in favor of neither party is appropriate.

"A design patent is infringed if, in the eye of an ordinary observer, giving such attention as a purchaser usually gives, two designs are substantially the same, if the resemblance is such as to deceive such an observer, inducing him to purchase one supposing it to be the other." Ethicon Endo-Surgery, Inc. v. Covidien, Inc., 796 F.3d 1312, 1335 (Fed. Cir. 2015) (quoting Egyptian Goddess, Inc. v. Swisa, Inc., 543 F.3d 665, 670 (Fed. Cir. 2008)) (alterations and internal quotation marks omitted). In making this determination, differences between the patented design and the claimed design "must be evaluated in the context of the claimed design as a whole, and not in the context of separate elements in isolation." Id. Thus, "[a]n element-by-element comparison, untethered from application of the ordinary observer inquiry to the overall design, is procedural error." Id.; see also Payless Shoesource, Inc. v. Reebok Int'l Ltd., 998 F.2d 985, 991

(Fed. Cir. 1993) (explaining that, because the "ultimate question requires determining whether the effect of the whole design is substantially the same[,] . . . minor differences between a patented design and an accused article's design cannot, and shall not, prevent a finding of infringement" (internal quotation marks and alterations omitted)).

Infringement is a question of fact, which the patent holder must prove by a preponderance of the evidence. See Braun Inc. v. Dynamics Corp. of Am., 975 F.2d 815, 819 (Fed. Cir. 1992). Accordingly, summary judgment in favor of an alleged infringer is appropriate "where the claimed and the accused designs are 'sufficiently distinct' and 'plainly dissimilar," because, in such cases, "the patentee fails to meet its burden of proving infringement as a matter of law." Ethicon Endo-Surgery, Inc., 796 F.3d at 1335. Thus, in Ethicon, the United States Court of Appeals for the Federal Circuit concluded that the district court had appropriately granted summary judgment in favor of the alleged infringer, where "there could be no genuine dispute that the claimed designs and the design of [the] accused [products] were plainly dissimilar because they simply did not look alike." Id.

Conversely, summary judgment in favor of the *patent holder* is appropriate only where there can be no genuine dispute that an ordinary observer, with knowledge of the prior art, would be deceived into thinking that the designs were the same. See, e.g., Famosa, Corp. v. Gaiam, Inc., No. 11-cv-5703, 2012 WL 573999, at *3 (S.D.N.Y. Feb. 22, 2012) (granting summary judgment to the patent holder on the issue of infringement and explaining that "not only are the designs substantially similar, they are nearly identical," such that "the accused product infringes the [design] patent as a matter of law").

After careful examination of all pertinent products "in the context of the claimed design as a whole," I conclude that this case presents neither of these scenarios in which summary judgment is appropriate. Ethicon Endo-Surgery, Inc., 796 F.3d at 1335. Rather, a reasonable factfinder could find in favor of either party on the issue of infringement.

Reproduced again below is a side-by-side comparison of the Accused Products and the corresponding figures of the D'839 Patent:



Plaintiff emphasizes the ways in which the D'839 Patent and the Accused Products are very similar. Specifically, Plaintiff notes that each design contains Mickey Mouse ear shaped wings, and that these wings have an "upswept" configuration—or, in other words, are angled

away from the insertion point of the sheath. Additionally, Plaintiff notes that, in both the D'839 Patent and the Accused Products, the top and bottom surfaces of the wings have similar configurations of "ribs"—which are the raised lines visible on the surfaces of the wings. Plaintiff notes that in both the D'839 Patent and each of the Accused Products, the ribs are equally-spaced, are oriented parallel to each other and perpendicular to the length of the wings, and generally conform to the shape of the wings by lengthening in the middle of each wing.

Defendants maintain that Plaintiff focuses too narrowly on the wings, ignoring the different hub designs. Defendants note that while the D'839 Patent calls for a tapered, coneshaped hub, three of the Accused Products—Super Sheath, Super Sheath 2.0, and Super Sheath Valved 2.0—have a hub that is "stepped." The different hub configurations are indicated by arrows below:



Super Sheath and Super Sheath 2.0

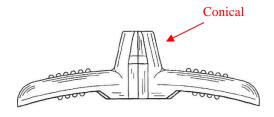


Figure 6 of the D'839 Patent



Super Sheath Valved 2.0



Super Sheath Valved

Defendants also contend that the Accused Products differ from the D'839 Patent in that each of the Accused Products have a "locking mechanism" that is *external*, whereas the D'839 Patent's locking mechanism is *internal*. The "locking mechanism" is the feature, located on the underside of the introducer that secures the sheath. Each of the locking mechanisms are indicated below by a rectangular box:



Super Sheath and Super Sheath 2.0

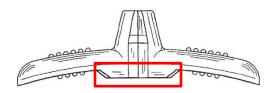


Figure 6 of the D'839 Patent



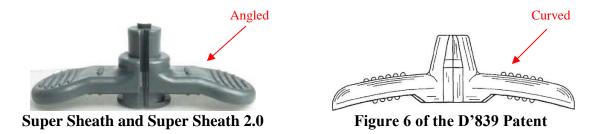
Super Sheath Valved 2.0



Super Sheath Valved

Defendants also maintain that there are significant differences in the wings of the D'839 Patent and those of the Accused Products. While there is an "upswept" appearance to the wings in each of the Accused Products, Defendants note that two of them—Super Sheath Valved and Super Sheath Valved 2.0—are swept up at a sharper angle. And while the other two products—Super Sheath and Super Sheath 2.0—are swept up at an angle closer to that shown in the figures of the D'839 Patent, Defendants note that their products have a more "angular construction." In other words, the wings of Super Sheath and Super Sheath 2.0 appear to extend straight out before

sweeping down at an angle, whereas the wings illustrated in the D'839 Patent appear to immediately curve downward from the hub. A side view is illustrative:



Defendants further note that Super Sheath Valved and Super Sheath Valved 2.0 each have "gussets"—which connect the upper portion of the hub with each of the wings. Arrows in the illustration below point to gussets in Super Sheath Valved and Super Sheath Valved 2.0, alongside the corresponding figure from the D'839 Patent, which lacks gussets.



Having considered the similarities and differences between the D'839 Patent and the Accused Products, I conclude that the designs are neither "plainly dissimilar" nor "nearly identical," such that summary judgment in favor of either party on the issue of infringement would be appropriate.

The Mickey Mouse ear shape of the wings, their upswept configuration, and the orientation of the ribs on the top and bottom surfaces, are all visually prominent features common to the D'839 Patent and each of the Accused Products. Accordingly, despite the differences pointed out by Defendants, I cannot conclude that the *overall* designs are so plainly

dissimilar that no reasonable jury could conclude that the designs are substantially the same. See, e.g., Amini Innovation Corp. v. Anthony California, Inc., 211 F. App'x 938, 941 (Fed. Cir. 2007) (reversing district court's grant of summary judgment in favor of an alleged infringer of a design patent, and noting that, based on a "compari[son] [of] the overall visual appearance of [the accused and patented designs], we are not prepared to say that a jury could not reasonably conclude that [the] accused design is similar enough in ornamental appearance to [the patented] design that an ordinary observer would be likely to purchase one . . . thinking it was the other"); Durdin v. Kuryakyn Holdings, Inc., 440 F. Supp. 2d 921, 933 (W.D. Wisc. 2006) (denying summary judgment in favor of an alleged infringer of a design patent, despite "observable differences between the [patented and accused] designs," because "[j]urors, who are ordinary observers, could examine the designs and reasonably conclude that they are substantially similar").

However, the differences pointed out by Defendants are visually significant enough that I also cannot conclude that the designs are "nearly identical." <u>Famosa, Corp.</u>, 2012 WL 573999, at *3. Therefore, I cannot conclude that no reasonable juror could find other than that the designs are substantially similar. Accordingly, both Plaintiff's and Defendants' motions for summary judgment will be denied as to the issue of infringement, and this issue will have to be decided by a factfinder.

B. *Invalidity*

In addition to seeking summary judgment on the issue of infringement, the parties have cross-moved for summary judgment on several grounds of invalidity raised by Defendants. Plaintiff argues that Defendants cannot meet their burden of proving these invalidity defenses by clear and convincing evidence. Defendants maintain that there is no genuine dispute of material

fact as to several of these invalidity defenses, and that the D'839 Patent is invalid as a matter of law.

Like utility patents, design patents are presumed to be valid. Ethicon Endo-Surgery, Inc., 796 F.3d at 1328. Accordingly, an alleged infringer "has the burden to prove invalidity of [a design patent] by clear and convincing evidence." Id. "Although an exact definition is elusive, clear and convincing evidence has been described as evidence that places in the ultimate factfinder an abiding conviction that the truth of its factual contentions are highly probable." Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1360 (Fed. Cir. 2007) (internal quotation marks and citations omitted).

With this standard in mind, I turn to whether a reasonable factfinder could find in favor of Defendants as to the invalidity defenses at issue in the parties' cross-motions for summary judgment. Seven such defenses are at issue here: (1) indefiniteness; (2) the on-sale bar; (3) inventorship; (4) inequitable conduct; (5) obviousness; (6) prosecution history estoppel; and (7) patent misuse. Plaintiff contends that Defendants cannot meet their burden as to any of these defenses, which thus fail as a matter of law. Defendants respond that, as to the first three defenses, there is no genuine dispute of material fact, and that they have established invalidity as a matter of law such that summary judgment in their favor is warranted. As to the last four defenses, Defendants contend that there are material facts in dispute, such that Plaintiff's motion for summary judgment should be denied. I address each of these seven invalidity defenses in turn.

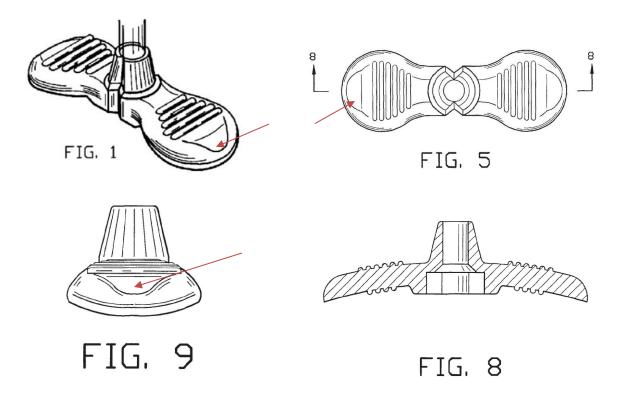
1. Indefiniteness

Defendants contend that the D'839 Patent is invalid as indefinite, based on a number of alleged inconsistencies in the patent's figures. Both Plaintiff and Defendants seek summary judgment as to this issue.

A design patent is invalid as indefinite under 35 U.S.C. § 112 "if one skilled in the art, viewing the design as would an ordinary observer, would not understand the scope of the design with reasonable certainty based on the claim and visual disclosure." In re Maatita, 900 F.3d 1369, 1377 (Fed. Cir. 2018). The visual disclosure of a design patent may fail to inform an ordinary observer of the scope of the claim where the patent includes "multiple, internally inconsistent drawings." Id. However, such inconsistencies do not render the patent indefinite where "they do not preclude the overall understanding of the drawing as a whole." Id. (internal quotation marks omitted). Rather, inconsistencies render the patent invalid only where they "are of such magnitude that the drawings, taken as a whole, fail to inform, with reasonable certainty, those skilled in the art about the overall appearance of the design." Deckers Outdoor Corp. v. Romeo & Juliette, Inc., 2016 WL 7017219, at *4 (C.D. Cal. Dec. 1, 2016). This is a question of law to be decided by the court. See Amgen Inc. v. F. Hoffman-La Roche Ltd, 580 F.3d 1340, 1371 (Fed. Cir. 2009).

Defendants argue that the D'839 Patent is indefinite in light of four inconsistencies in its figures: (1) the presence of a "scallop" on each wing; (2) the location of a facet, or "step," in the hub; (3) the angle of the "proximal boss;" and (4) the number of ribs—five or six. For the reasons discussed below, I conclude that these four purported inconsistencies, considered individually or together, do not render the D'839 Patent indefinite.

First, Defendants argue that it is unclear whether the D'839 Patent calls for each wing to have a "scallop"—that is, an indentation or depression in the surface of the wing. Defendants contend that this feature is present in Figures 1, 2, 3, 4, 5, and 9, as indicated by the arrows below, but absent from Figure 8, which shows a cross-sectional view:

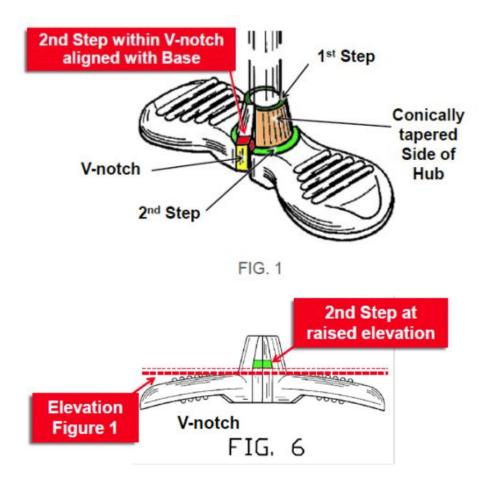


Plaintiff responds that the patented design includes no such "scallop," and that the curved line present in Figures 1, 5, and 9 above is merely "a drawing convention to show the transition from the upper surface of the [wing] to the rounded end." (Pl.'s Opp'n 7.)

Defendants have not provided evidence that the curved line represents a scallop feature rather than merely the downward curvature of the wing. Defendants' expert, Richard Meyst, does not explain his conclusion that the curved line represents a scallop. (See Expert Report of Richard Meyst (hereinafter "Meyst Report") ¶ 103.) Accordingly, Defendants have not established that a scallop feature is even present in the figures that they point to. And even if such a feature is present, it is not clear that the omission of the feature from the side and cross-

sectional views is an omission of such magnitude that it renders the *overall* appearance of the design uncertain.

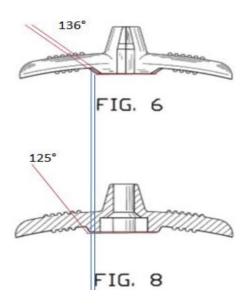
Second, Defendants contend that the D'839 Patent is inconsistent as to the location of a facet, or "second step", within the V-shaped "notch" on the hub. Defendants contend that Figures 1, 2, and 5 illustrate the second step at the base of the hub, but that Figures 3 and 6 show the second step at a higher elevation. Defendants' brief includes the following illustrations in support of their position:



Plaintiff responds that the difference in the location of the second step is minor and does not significantly affect the overall visual impression, as it is "barely visible on an actual product" embodying the design. (Pl.'s Opp'n 6.) I agree with Plaintiff that this inconsistency—to the

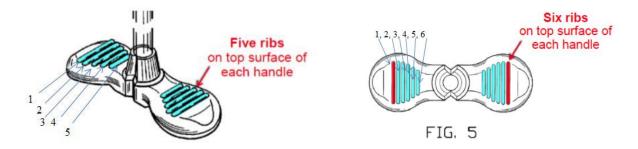
extent that it is, in fact, an inconsistency, and not merely the result of a difference in perspective between the figures—is minor, and thus does not render the overall visual impression of the design uncertain.

Third, Defendants contend that the figures of the D'839 Patent inconsistently depict the "angle of the proximal boss," which is the angle between the base of the underside of the introducer, and the surface that is rising toward the wings. Defendants maintain that Figure 6 (the side view) shows the angle to be about 136 degrees, whereas Figure 8 (the cross-sectional view) shows the angle to be about 125 degrees. Defendants' brief supports this contention with the illustration below.



Plaintiff responds that this difference in angle is minor and "only discernable when magnifying the drawings well beyond the actual size of the item." (Pl.'s Opp'n 6.) I agree with Plaintiff that a eleven-degree variation in this angle makes little, if any, difference to the overall visual impression of the design, and thus does not render the design uncertain.

Fourth and finally, Defendants point to the exact number of ribs on the top surface of the wings. While Figures 1 and 2 show five ribs, Figures 3 through 6, and 8, show six ribs. Defendants' brief provides the following illustrations:



Plaintiff responds that whether there are five or six ribs is not significant. What matters, Plaintiff argues, is the orientation of the ribs on the surface. Specifically, Plaintiff notes that the ribs are equally spaced, run parallel to each other and perpendicular to the length of the wings, and generally conform to the shape of the wings, getting shorter as the wing curves in towards the hub. I agree with Plaintiff that the precise number of ribs—five or six—does not significantly affect the overall visual impression of the design.

In sum, considered separately or together, the inconsistencies identified by Defendants—to the extent that they are, in fact, inconsistent—do not render the D'839 Patent indefinite, because they do not prevent an ordinary observer from determining the overall visual impression of the design. See Deckers Outdoor Corp., 2016 WL 7017219, at *4 (concluding that a design patent for a boot was not indefinite where "the Court [was] not 'clearly' convinced that the discrepancies [in the patent figures] [were] of such magnitude that a boot designer and manufacturer could not determine with reasonable certainty the overall appearance of the boot'). Accordingly, as to indefiniteness, Plaintiff's motion for summary judgment will be granted, and Defendants' motion denied.

2. On-Sale Bar

Defendants next contend that the D'839 Patent is invalid because a product embodying the patented design was offered for sale more than one year before Plaintiff applied for the patent. Plaintiff responds that the product was not offered for sale before that date. Both parties seek summary judgment as to this issue.

A patent is invalid under the "on-sale bar" set out in 35 U.S.C. § 102(b), if, more than one year before the filing of the patent application with the PTO, two conditions are met: "(1) the claimed invention [was] the subject of a commercial offer for sale; and (2) the invention [was] ready for patenting." Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc., 726 F.3d 1370, 1375 (Fed. Cir. 2013). To be "the subject of a commercial offer for sale," the patented design need not have been actually sold. Id. Rather, an *offer* to sell "is sufficient so long as it is sufficiently definite that another party could make a binding contract by simple acceptance." Id. (internal quotation marks omitted).

Plaintiff filed his patent application on February 7, 2000. Thus, the critical date for purposes of the on-sale bar is February 7, 1999. If a product embodying the claimed design was offered for sale before that date, then the D'839 Patent is invalid.

Here, Defendants argue that the on-sale bar applies because, in January 1999, Eddings offered to sell a product embodying the patented design to a company called Boston Scientific. As evidence, Defendants offer two letters that Eddings sent to Boston Scientific on behalf of his company, Xentek Medical, during that month: one on January 8, 1999, and one on January 25, 1999. Plaintiff responds that neither letter constitutes a sufficiently definite offer to trigger the on-sale bar.

Whether a communication constitutes a sufficiently definite offer is a question of law, governed not by a specific state's law of contracts, but rather by the case law of the Federal Circuit interpreting "the law of contracts as generally understood." Grp. One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1047 (Fed. Cir. 2001). In ascertaining the law of contracts, the Federal Circuit looks primarily to the Uniform Commercial Code and the Restatement of Contracts. See id. at 1047-48.

Section 26 of the Restatement (Second) of Contracts distinguishes communications that are definite offers from those that are merely "preliminary negotiations." The latter consists of communications in which "the person to whom [the communication] is addressed knows or has reason to know that the person making it does not intend to conclude a bargain until he has made a further manifestation of assent." Restatement (Second) of Contracts § 26 (1981). Such communications include price quotations, which the commentary to the Restatement describes as follows:

c. Quotation of price. A "quotation" of price is usually a statement of price per unit of quantity; it may omit the quantity to be sold, time and place of delivery, terms of payment, and other terms. It is sometimes associated with a price list or circular, but the word "quote" is commonly understood as inviting an offer rather than as making one, even when directed to a particular customer. But just as the word "offer" does not necessarily mean that an offer is intended, so the word "quote" may be used in an offer. In determining whether an offer is made relevant factors include the terms of any previous inquiry, the completeness of the terms of the suggested bargain, and the number of persons to whom a communication is addressed.

Restatement (Second) of Contracts § 26 cmt. c (1981).

Applying these principles to the two letters that Eddings sent to Boston Scientific in January 1999, it is clear that they constitute preliminary negotiations, rather than definite offers to sell.

First, both letters use the word "quotation" and not the word "offer." The January 8 letter uses the word three times: "Thank you for the opportunity to provide this *quotation* for the Medi-Tech Peelable Sheath Set. . . . When we first received this request for *quotation* we were under the mistaken impression that you wanted the exact configuration of the drawing that was provided Subsequently, we have learned that this is not the case and are pleased to submit this *quotation* for a product of our design." (Petruzzi Decl., Ex. 46 (emphasis added.)) The January 25 letter likewise uses the term "quotation": "Based on our discussions, Xentek Medical will prepare a *quotation* on the larger sizes of peelable sheath introducers." (Petruzzi Decl., Ex. 47 (emphasis added.))

While use of the term "quotation" rather than "offer" is not, by itself, dispositive, other language in both the January 8 and January 25 letters suggests an invitation to further negotiations rather than an offer for immediate acceptance. The January 8 letter concludes: "I appreciate the opportunity to provide this quotation and *look forward to discussing your requirements in person.*" (Petruzzi Decl., Ex. 46 (emphasis added.)) Likewise, Eddings closes the January 25 letter by noting that he "would like to have the opportunity to review your requirements and provide a project plan to complete this project." (Petruzzi Decl., Ex. 47 (emphasis added.)). Courts have held similar language to constitute preliminary negotiations rather than definite offers. See, e.g., Goss Int'l Americas, Inc. v. Graphic Mgmt. Assocs., Inc., 739 F. Supp. 2d 1089, 1121 (N.D. Ill. 2010) (holding that certain "budgetary proposals" were preliminary negotiations that did not trigger the on-sale bar where the proposals "thanked the [recipient] for the opportunity to submit this information as we look forward to working very closely with you on this project").

Defendants emphasize that the January 8 letter included several specific terms, including a payment term ("on a net 30-day basis"), a shipment term ("FOB Athens, Texas"),³ and a delivery conditions term ("non-sterile"), in addition to providing four choices of unit quantities and their corresponding per-unit prices. While the inclusion of these terms does cut in favor of interpreting the January 8 letter as a definite offer, this consideration is ultimately outweighed by the other language discussed above, as well as by the fact that another key term, a specific delivery time, was left unspecified. See, e.g., Goss Int'l Americas, Inc., 739 F. Supp. 2d at 1121-1122 (holding that a document did not constitute an offer despite the inclusion of "some terms" where other terms, including "specific time of delivery" and "a firm price term" were "left openended and subject to change").

Because the January 8 and January 25 letters constitute preliminary negotiations, rather than definite offers, they do not trigger the on-sale bar and thus do not render the D'839 Patent invalid. Accordingly, Plaintiff's motion for summary judgment as to this issue will be granted and Defendants' motion denied.

3. <u>Inventorship</u>

Defendants next contend that the D'839 Patent is invalid because Plaintiff is not the sole inventor of the claimed design and that the design was invented, at least in part, by Gillespie. Plaintiff responds that he is the sole inventor of the design, and that Defendants cannot meet their

³ "FOB" stands for "free on board," which is "a mercantile-contract term allocating the rights and duties of the buyer and the seller of goods with respect to delivery, payment, and risk of loss, whereby the seller must clear the goods for export, and the buyer must arrange for transportation." <u>Black's Law Dictionary</u> 737 (9th ed. 2009).

burden of proving otherwise.⁴ Both Plaintiff and Defendants seek summary judgment on this issue.

As with utility patents, a design patent may only issue to a person who "invents" the design. 35 U.S.C. § 171. Thus, the "naming of the correct inventor or inventors [is] a condition of patentability; failure to name them renders a patent invalid." <u>Pannu v. Iolab Corp.</u>, 155 F.3d 1344, 1350 (Fed. Cir. 1998).

"An inventor under the patent laws is the person or persons who conceived the patented invention." Hoop v. Hoop, 279 F.3d 1004, 1007 (Fed. Cir. 2002) (internal quotation marks omitted). A person conceives of an invention when he "form[s] in [his] mind . . . a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." Id. In turn, "[a]n idea is sufficiently 'definite and permanent' when 'only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998).

⁴ In addition to arguing that Defendants' inventorship defense fails on the merits, Plaintiff contends that the defense fails for two procedural reasons. First, Plaintiff contends that inventorship issues "are not in this case" because they were stricken from Defendants' Third Amended Answer. (Pl.'s Opp'n 15; see also Pl.'s Mem. in Supp. 26 n.12.) While I did strike a *footnote* that related to inventorship from Defendants' Third Amended Answer because Defendants had added the footnote without leave to do so, I did not disturb the *body* of Defendants' Third Affirmative Defense within their Third Amended Answer, which asserts invalidity on multiple grounds, including "the requirements set forth in 35 U.S.C. § . . . 102," which includes inventorship. Plaintiff did not challenge the legal sufficiency of the Third Affirmative Defense. Accordingly, Plaintiff is incorrect that inventorship issues "are not in the case."

Second, Plaintiff contends that Defendants' inventorship defense is precluded by the doctrine of collateral estoppel, noting that inventorship of the D'839 Patent was at issue in the Eddings Suit, in which another district court upheld the validity of the patent. However, because Defendants were not parties to the Eddings Suit, nor in privity with any of the parties to the Eddings Suit, the outcome of the Eddings Suit may not be used as collateral estoppel against them in this case. See Allen Archery, Inc. v. Browning Mfg. Co., 819 F.2d 1087, 1091 (Fed. Cir. 1987) (holding that a patent holder could not use the outcome of a previous case, in which the patent-in-suit's validity was upheld, as collateral estoppel against an alleged infringer, because the alleged infringer was not a party to the previous case).

While a "conceived invention must include every feature of the subject matter claimed in the patent," an invention may be conceived by "co-inventors," each of whom need only "perform . . . a part of the task which produces the invention." Ethicon, Inc., 135 F.3d at 1460. However, a person does not become a co-inventor "by merely assisting the actual inventor after conception of the claimed design." Id. Thus, in the design patent context, a person does not become a co-inventor by "merely refin[ing] and perfect[ing]" the inventor's sketch of the design.

See Hoop, 279 F.3d 1004, 1008 (granting a preliminary injunction to patent holders in an infringement action, notwithstanding the alleged infringers' claim to have invented the claimed design, where the alleged infringers had merely been hired by the patent holders "to create detailed drawings and three-dimensional models for a patent application" based on the sketches provided by the patent holders).

"While inventorship is a question of law, it is based on underlying facts." <u>Safco Prod. Co. v. Welcom Prod., Inc.</u>, 799 F. Supp. 2d 967, 978 (D. Minn. 2011) (internal quotation marks and alterations omitted) (quoting <u>Univ. of Pittsburgh v. Hendrick</u>, 573 F.3d 1290, 1297 (Fed. Cir. 2009)). Here, as discussed below, Plaintiff's account of the facts surrounding the invention of the patented design diverges substantially from the accounts of Eddings and Gillespie. Because the material facts surrounding who invented the claimed design are in dispute, summary judgment in favor of either Plaintiff or Defendants on the issue of inventorship is not appropriate.

a. Plaintiff's Account

Plaintiff maintains that he, and he alone, invented the design embodied by the D'839 Patent. In support of his position, he has submitted a declaration stating that, in 1998, he "conceived a new introducer handle design involving a two[-]part Mickey Mouse eared handle, with an upswept configuration, having ribs on the top and bottom of the handle," which ribs

"were oriented on the two surfaces and generally conformed to the outer periphery of the rounded handles." (Junker Decl. ¶ 5.) Plaintiff declares that he "disclosed all of the details" of this design to Eddings during a meeting in August 1998, conducted under a non-disclosure agreement, believing that Eddings' company, Galt Medical, "would be capable of making [his] device." (Id. ¶¶ 6-7.) Thereafter, according to Plaintiff's declaration, Galt Medical prepared "a prototype drawing of [Plaintiff's] new design," as well as a three-dimensional model, though this model "did not include the rounded Mickey Mouse ears." (Id.)

After receiving this model, Plaintiff sent a fax to Eddings advising that he "would really like to see larger (wider) handles," because "[t]he prospective customers seemed to like this design." (Junker Decl. ¶ 9; Petruzzi Decl., Ex. 12.) According to Plaintiff, Gillespie then integrated the "large rounded ear Mickey Mouse" handles into subsequent drawings, which Gillespie prepared and shared with Plaintiff. (Junker Decl. ¶ 11.)

Plaintiff contends that "[o]ver the next year and [a] half, [Eddings' company] Xentek [Medical] proceeded to refine the CAD [computer-aided design] drawings for the manufacture of a device which included the ornamental handle." (Junker Decl. ¶ 12.) Plaintiff maintains that Gillespie provided him copies of these CAD drawings, because these drawings were "developed for [Plaintiff], at [Plaintiff's] direction." (Id. ¶ 13.) Plaintiff declares that he then provided these drawings to his "patent attorney and . . . draftsman," who used them to create the drawings that Plaintiff ultimately submitted to the PTO with his application for what became the D'839 Patent. (Id.)

b. Eddings and Gillespie's Account, Relied on by Defendants

The accounts of Eddings and Gillespie, on which Defendants rely, substantially diverge from Plaintiff's account. Gillespie provided a declaration stating, contrary to Plaintiff's declaration, that he never "serve[d] as a draftsman for the purpose of documenting . . . any ideas originating from [Plaintiff]." (Gillespie Decl. ¶ 4.) Rather, Gillespie declares, he and Eddings created the design for an introducer, to which Plaintiff only contributed "a suggestion . . . that the tear-away introducer sheath hub exhibit 'a wider, more bulbous profile' if viewed from the long axis of the component." (Id.) Gillespie admits that he "provided copies of drawings" of this design to Plaintiff, but declares that he "had no knowledge that [Plaintiff] intended to use these drawings to support an application to be filed with the [PTO]." (Id. ¶ 6.)

Gillespie declares that he conceived of several of the design elements embodied in the D'839 Patent. Specifically, he declares that he conceived of "the backswept wing shape of the handles," as a means of "provid[ing] the holder of the handle more leverage." He also declares that he invented "[t]he rearward-extending face of the hub," and the "rectangular lines near the center of the hub." (Gillespie Decl. ¶¶ 7-9.)

Like Gillespie, Eddings declares that he and Gillespie designed an introducer "without any contribution from [Plaintiff] except to make the handles bigger." (Eddings Dep. at 108:5-14.) Indeed, when Eddings was asked in his deposition what contribution Plaintiff made to the design illustrated in Figures 5 through 7 of the D'839 Patent, Eddings responded "absolutely none," stressing that "[t]hese were my drawings." (Id. at 136:13-21.)

In light of these widely diverging accounts of the circumstances surrounding the invention of the patented design, summary judgment in favor of either party would be inappropriate. See, e.g., Safco Prod. Co., 799 F. Supp. 2d at 986-991 (denying cross-motions for

summary judgment on the issue of inventorship of a design patent where the witness' testimony "paint[ed] two vastly different—and quite irreconcilable—factual pictures"). A reasonable jury could credit Eddings and Gillespie's account of what occurred in late 1998, and conclude that Plaintiff was not the sole inventor of the patented design. However, a reasonable jury could also conclude—as a jury did in the previous Eddings Suit—that there is not clear and convincing evidence that someone other than Plaintiff was an inventor of the design. Accordingly, both Plaintiff's and Defendants' motions for summary judgment as to inventorship will be denied.

4. Obviousness

Defendants also contend that the D'839 Patent is invalid because it is obvious in light of the prior art. While Defendants do not move for summary judgment as to this defense, conceding that there are material facts in dispute, Plaintiff does move for summary judgment as to this issue, contending that the defense fails as a matter of law.

A design patent is invalid for obviousness under 35 U.S.C. § 103 if "the claimed design would have been obvious to a designer of ordinary skill who designs articles of the type involved." Apple, Inc. v. Samsung Elecs., 678 F.3d 1314, 1329 (Fed. Cir. 2012). To conclude that this standard is met, the court must "find a single reference [in the prior art] . . . the design characteristics of which are basically the same as the claimed design." Id. While "other references may be used to modify [this primary reference] to create a design that has the same overall visual appearance as the claimed design," the "secondary references may only be used to modify the primary reference if they are so related to the primary reference that the appearance of certain ornamental features in one would suggest the application of those features to the other." Id. at 1330.

"Obviousness is a question of law . . . , based on underlying factual questions" MRC Innovations, Inc. v. Hunter Mfg., LLP, 747 F.3d 1326, 1331 (Fed. Cir. 2014). "The underlying factual inquiries include: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of non-obviousness." Id. Accordingly, summary judgment is appropriate only "when the factual inquiries into obviousness present no genuine issue of material facts." Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 716 (Fed. Cir. 1991).

In support of their asserted obviousness defense, Defendants identify as a primary reference a utility patent obtained by Gillespie, U.S. Patent Number 6,336,914 (the "Gillespie Patent"), as modified by three other secondary references in the prior art: (1) U.S. Patent Number 5,885,217 (the "Gisselberg Patent"); (2) U.S. Patent Number 5,762,630 (the "Bley Patent"); and (3) U.S. Patent Number 4,772,266 (the "Groshong Patent"). Plaintiff maintains that Defendants' argument "that [the Gillespie Patent] is a primary reference is completely undercut by the patent office having already determined it is non-enabling art and not anticipatory in the reexamination." (Pl.'s Mem. in Supp. 21.)

Plaintiff is correct that where the PTO has reexamined the patent-in-suit, and rejected the prior art references that the alleged infringer contends invalidate the patent, the alleged infringer "has the added burden of overcoming the deference due to the PTO." <u>PowerOasis, Inc. v. T-Mobile USA, Inc.</u>, 522 F.3d 1299, 1304 (3d Cir. 2008). However, even in such a case, the PTO's decision is not binding on the court, which must still determine whether the patent is invalid as obvious. And here, Defendants have pointed to two patents in the prior art—the Groshong Patent

and the Gisselberg Patent—that the PTO does not appear to have considered.⁵ Importantly, Plaintiff does not address these two patents in his briefing, nor does Plaintiff's expert, Peter Bressler, address these prior art references in his expert report. Rather, both merely parrot the PTO's decision.

Accordingly, Plaintiff has not met his initial burden in moving for summary judgment of demonstrating that there is no genuine dispute of material fact regarding Defendants' obviousness defense. Both the scope and content of the prior art and the differences between the claimed invention and the prior art, appear to be in genuine dispute. Plaintiff's motion for summary judgment as to obviousness will therefore be denied.

5. Inequitable Conduct

Defendants also contend that the D'839 Patent is invalid due to inequitable conduct on the part of Plaintiff. Defendants do not move for summary judgment as to this defense, but Plaintiff does, contending that the defense fails as a matter of law.⁶

To render a patent unenforceable based on the patentee's inequitable conduct during the application process, an alleged infringer must prove "by clear and convincing evidence that the patent applicant made misrepresentations or omissions material to patentability, that he did so with the specific intent to mislead or deceive the PTO, and that deceptive intent was the single most reasonable inference to be drawn from the evidence." Ohio Willow Wood Co. v. Alps S., LLC, 813 F.3d 1350, 1357 (Fed. Cir. 2016). If an alleged infringer proves such an intentional

⁵ Defendants contend that the Bley Patent was not before the PTO. (Defs.' Opp'n 12.) But the PTO's reexamination decision shows that it considered and rejected the Bley Patent as a secondary reference in its obviousness analysis. (Def.'s Mot., Ex. 7 at ¶ 11.)

⁶ Plaintiff also moves for summary judgment as to Defendants' Fifth Affirmative Defense, which lists a number of equitable defenses including "unclean hands." Because an inequitable conduct defense is broader in scope and includes a defense of "unclean hands," the analysis as to inequitable conduct below applies equally to Defendants' unclean hands defense. See Therasense, Inc. v. Becton, Dickinson, & Co., 649 F.3d 1276, 1287 (Fed. Cir. 2011).

and material misrepresentation by clear and convincing evidence, then the court must "balance the substance of those . . . proven facts and all the equities in the case to determine whether the severe penalty of unenforceability should be imposed." <u>Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.</u>, 537 F.3d 1357, 1367 (Fed. Cir. 2008). But a court must first determine whether an intentional and material misrepresentation was made, and may not enter summary judgment on this issue where there are material facts in dispute.

The parties' arguments as to inequitable conduct mirror those as to inventorship discussed in Part III.B.3, above. Defendants maintain that Plaintiff was not the inventor of the design embodied by the D'839 Patent and that, accordingly, a reasonable factfinder could conclude that Plaintiff intentionally misled the PTO when he applied for a patent using drawings created by Gillespie without naming Gillespie as an inventor. Plaintiff responds that he and he alone invented the patented design and that, accordingly, he did not make any misrepresentation to the PTO by failing to name Gillespie.

Because who invented the design embodied in the D'839 Patent remains in genuine dispute, Plaintiff's motion for summary judgment as to inequitable conduct will be denied.

6. <u>Prosecution History Estoppel</u>

Plaintiff also seeks summary judgment on Defendants' Sixth Affirmative Defense, prosecution history estoppel, which Plaintiff contends lacks any factual support.

Prosecution history estoppel is a "rule of patent construction" that requires the claims of a patent be interpreted consistent with the prosecution proceedings before the PTO. <u>Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.</u>, 535 U.S. 722, 733 (2002). Thus, when a patentee narrows the scope of his patent during the prosecution proceedings in an effort to avoid invalidity, he may not then turn around and claim the previously conceded scope in an action for

patent infringement. <u>See id.</u> (explaining that a patentee's narrowing of the claim scope to avoid a finding of invalidity by the PTO acts "as a concession that the invention as patented does not reach as far as the original claim").

Here, however, Defendants have not identified any position that Plaintiff took before the PTO to narrow the scope of the patented design in order to avoid invalidity. Defendants contend that Plaintiff "fail[ed] to amend the drawings of his patent application so the drawings only cover the 'Mickey Mouse' shape of the illustrated design," and that this estops him from "trying to now argue that the claim covers less than what is shown in solid line[s] in the drawings." (Defs.' Opp'n 25). But even if a failure to amend a patent constitutes grounds for applying prosecution history estoppel, I have already construed the D'839 Patent as including not only the Mickey Mouse ear shape of the wings, but everything illustrated in solid lines, including the hub. Thus, it is not clear what further relief Defendants seek through an assertion of a prosecution history estoppel defense.

Defendants also contend that Plaintiff "abandoned [a] reissue application that attempted to amend the [s]pecification of the [D'839 Patent]" and that this "estops [Plaintiff] from trying to recapture what he previously gave up in that reexamination proceeding and his related reissue proceeding," specifically a "priority [date] prior to the filing date of the [D'839 Patent] (February 7, 2000)." (Defs.' Opp'n 25.). However, Defendants cite no case in which prosecution history estoppel doctrine has been applied to the abandonment of a reissue application, nor any case in which the doctrine has been applied to estop a patent holder from claiming an earlier priority date.

Because Defendants have not articulated any basis for the application of prosecution history estoppel, Plaintiff's motion for summary judgment as to this defense will be granted.

7. Patent Misuse

Plaintiff also seeks summary judgment as to Defendants' Seventh Affirmative Defense, patent misuse. As with prosecution history estoppel, Plaintiff contends that there is no factual support for the defense.

Patent misuse applies where a patent holder has "impermissibly broadened the physical or temporal scope of the patent grant with anticompetitive effect." Windsurfing Int'l Inc. v. AMF, Inc., 782 F.2d 995, 1002 (Fed. Cir. 1986) (internal quotation marks omitted). For example, an accused infringer may invoke the doctrine where the patent holder has imposed "restrictive conditions on licenses" of the patented product, such as a tying arrangement that requires a would-be licensee to purchase an additional, unneeded product from the patent holder. See Princo Corp. v. Int'l Trade Comm'n, 616 F.3d 1318, 1328 (Fed. Cir. 2010). "What patent misuse is about, in short, is patent leverage, i.e., the use of the patent power to impose overbroad conditions on the use of the patent in suit that are not within the reach of the monopoly granted by the Government." Id. at 1331 (internal quotation marks omitted).

Defendants do not contend that Plaintiff has leveraged the D'839 Patent to impose additional conditions on a would-be licensee or purchaser. Rather, Defendants contend that Plaintiff has committed patent misuse by "asserting a claim of patent infringement based on an impermissibly broadened scope of what the claim of the patent covers," and did so "knowing [that] he was not the inventor of the claimed design." (Defs.' Opp'n 25.) However, Defendants cite no case in which the doctrine has been applied to render a patent unenforceable merely because the patent holder has brought an action for patent infringement that he knows to be

meritless. And the United States Court of Appeals for the Federal Circuit has rejected similar uses of the patent misuse doctrine, explaining that the doctrine "has largely been confined to a handful of specific [anticompetitive] actions," and warning against expansion of the doctrine into "an open-ended pitfall." C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1373 (Fed. Cir. 1998) (holding that a "jury instruction on patent misuse" was overbroad, where it "focused primarily on the charge that [the patent holder] was attempting to enforce the patents against goods known not to be infringing").

Because Defendants have not identified any facts supporting a claim for patent misuse, Plaintiff's motion for summary judgment as to this defense will be granted.

C. Damages

Plaintiff also moves for summary judgment on the issue of damages, raising two damages-related arguments. First, Plaintiff contends that one measure of damages, the amount of Defendants' profits from sales of the Accused Products, is undisputed. Second, Plaintiff argues that Defendants' Fourth Affirmative Defense—in which Defendants contend that Plaintiff's damages are limited due to Plaintiff's failure to mark patented products—fails as a matter of law. For the reasons discussed below, Plaintiff's motion for summary judgment on the issue of damages will be denied.

First, I need not decide whether the amount of Defendants' profits is in genuine dispute, because a trial is required on the remaining issues of infringement and invalidity. This trial could result in a finding of non-infringement or invalidity, thus obviating any need to determine damages. Accordingly, Plaintiff's motion for summary judgment as to Defendants' profits will be denied.⁷

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⁷ For the same reason, Plaintiff's motion will be denied as to his additional argument that he is entitled to damages of at least \$250 per unit, pursuant to 35 U.S.C. § 289.

In his second argument, Plaintiff contends that Defendants' Fourth Affirmative Defense, in which Defendants posit that Plaintiff's damages for any infringement are limited because he failed to mark his patented products, fails as matter of law. For the reasons discussed below, Plaintiff's motion for summary judgment as to this issue will also be denied.

A patent holder that prevails in an action for patent infringement may generally recover damages for infringement extending back to six years before the filing of the complaint. 35 U.S.C. § 286. However, the patent marking statute, § 287, further limits damages where the patent holder fails to comply with certain marking requirements. Specifically, § 287 provides:

Patentees, and persons making, offering for sale, or selling within the United States any patented article for or under them, or importing any patented article into the United States, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice.

35 U.S.C. § 287(a) (emphasis added). Thus, under § 287, a patent holder that fails to mark his patented articles may only recover damages for infringement occurring after the alleged infringer received actual notice of infringement. And this limitation also applies where the patent holder's *licensees* have failed to mark the patented articles, because "the statute extends to persons making or selling any patented article for or under the patentee." <u>Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.</u>, 876 F.3d 1350, 1366 (Fed. Cir. 2017).

Although Defendants have raised § 287 as an "affirmative defense," it is not, in fact, an affirmative defense on which they, as the alleged infringers, bear the burden of proof. See Arctic Cat Inc., 876 F.3d at 1366 ("Section 287 is . . . a limitation on damages, and not an affirmative defense."). Rather, it is the Plaintiff, as the *patent holder*, that bears the burden of proving

compliance with § 287 by a preponderance of the evidence. Nike, Inc. v. Wal-Mart Stores, Inc., 138 F.3d 1437, 1446 (Fed. Cir. 1998). An alleged infringer bears only "an initial burden of production to articulate the products it believes are unmarked 'patented articles.'" Arctic Cat Inc., 876 F.3d at 1368.

Defendants contend that § 287 limits the damages Plaintiff may recover, because Plaintiff licensed his patented design to at least one third party, C.R. Bard, Inc. ("C.R. Bard"), which did not mark the products for which it obtained the license. In support of their position, Defendants note that C.R. Bard and Plaintiff entered into a "Patent License and Settlement Agreement" in November 2006, under which Plaintiff granted C.R. Bard a license for products embodying the patented design.

Plaintiff responds that § 287 does not apply to the products covered by this agreement, because the agreement "was merely a litigation settlement . . . for prior sales . . . , not an ongoing license where the licensee would be manufacturing and selling product that even could be marked." (Pl.'s Reply in Supp. 10.) Indeed, Plaintiff contends, the units covered by the agreement "were units Galt [Medical] manufactured," that had "already [been] produced [by Galt Medical] and resold by [C.R.] Bard." (<u>Id.</u>)

In support of Plaintiff's position that the only products licensed were ones that C.R. Bard had already sold, and were thus incapable of being marked, Plaintiff points to the agreement itself, which provides a license for the following products:

. . . any introducer . . . sold to [C.R. Bard] by Galt Medical Corp., Xentek Medical Inc. and/or James R. Eddings which was accused in [a patent infringement suit brought by Plaintiff against C.R. Bard] of infringing the [D'839] Patent, namely the particular introducer sheath that C.R. Bard purchased from Galt [Medical] for which sales information was provided in the [suit]. Nothing herein shall be construed as licensing any third party under the [D'839] Patent for any products sold by Galt Medical Products, Inc. that were not first sold to [C.R. Bard].

(Supp. J.A., Doc. No. 111-4, at SJM0001522.)

While this language from the agreement makes clear that the license extended only to products that Galt Medical, Xentek Medical, or Eddings sold to C.R. Bard, it does not make clear—as Plaintiff contends—that any licensed products had already been resold by C.R. Bard and were thus incapable of being marked.

Plaintiff further argues that this settlement was entered into "at a time when Galt [Medical] and [C.R.] Bard were already under a Court Order not to sell further product." (Pl.'s Reply in Supp. 10.) However, Plaintiff points to nothing in the record that makes clear that C.R. Bard did not, in fact, sell any products embodying the design of the D'839 Patent after entering into the licensing agreement with Plaintiff.

Because Plaintiff bears the burden of proof as to compliance with the marking statute, and because the record as to this issue is not fully developed, Plaintiff's motion for summary judgment will be denied.

IV. <u>DAUBERT MOTIONS</u>

In addition to cross-motions for summary judgment, both parties have filed motions to exclude the testimony of expert witnesses retained by the opposing party, pursuant to <u>Daubert v. Merrell Dow Pharmaceuticals, Inc.</u>, 509 U.S. 579 (1993). It is not clear from these motions whether the parties seek to exclude these experts' opinions from consideration in the cross-motions for summary judgment, at trial, or both. Accordingly, where these experts' opinions are necessary to my decision on the cross-motions for summary judgment, I will consider them below. Where they are not, I will deny them without prejudice to raise prior to trial.

Plaintiff seeks to exclude three of Defendants' experts: Richard Meyst, Gerald Mossinghoff, and Dana Trexler Smith.⁸ Defendants seek to exclude Plaintiff's expert, Peter Bressler. Both Plaintiff's and Defendants' <u>Daubert</u> motions will be denied, in part without prejudice and in part with prejudice.

A. Legal Standard

Federal Rule of Evidence 702 governs the admissibility of expert testimony, and provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 702 thus "embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741-43 (3d Cir. 1997)). In evaluating whether an expert opinion is admissible, a district court acts as a gatekeeper, excluding opinion testimony that does not meet these requirements. Id. However, "the court's role as a gatekeeper is not intended to serve as a replacement for the adversary system," because, "[a]s the Supreme Court noted in Daubert, vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Crowley v. Chait, 322 F. Supp. 2d 530, 536 (D. Del. 2004) (internal quotation marks and alterations omitted).

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⁸ Plaintiff also moved to exclude a fourth defense expert, Timothy Schweikert, based on Defendants' failure to produce his expert report. However, because Defendants have responded that they do not intend to call Schweikert as a witness, Plaintiff's motion as to him will be denied as moot.

The burden is on the party offering the evidence to establish admissibility by a preponderance of the evidence. Padillas v. Stork-Gamco, Inc., 186 F.3d 412, 418 (3d Cir. 1999).

With these principles in mind, I will address Plaintiff's and Defendants' <u>Daubert</u> motions in turn.

B. Plaintiff's Motion

Plaintiff seeks to exclude the testimony of three of Defendants' experts: Richard Meyst, Gerald Mossinghoff, and Dana Trexler Smith.

1. Richard Meyst

Meyst, a designer and engineer, provides opinions on both infringement and invalidity. Plaintiff contends that Meyst's testimony should be excluded because he "uses the wrong claim construction" of the D'839 Patent. (Pl.'s <u>Daubert Mot. 4.</u>) In support of this contention, Plaintiff notes that Meyst "attempts to put in words each detail in the drawings of the [D'839 Patent]." (<u>Id.</u>) However, the mere fact that Meyst provides a written description of the elements of the D'839 Patent does not contradict my claim construction. Indeed, Meyst's report appears to apply my claim construction, as it notes that "the scope of the claim . . . includes those elements shown in solid lines in figures 1-9." (Meyst Report ¶ 58.) Accordingly, Plaintiff's <u>Daubert motion</u> will be denied as to this issue.

Plaintiff also contends that Meyst's opinion that the D'839 Patent is indefinite should be excluded. Because I have concluded as a matter of law that the D'839 Patent is not indefinite, and will grant summary judgment in Plaintiff's favor as to indefiniteness, Plaintiff's <u>Daubert</u> motion as to this issue will be denied as moot.

Plaintiff next contends that Meyst's opinions on inventorship should be excluded because inventorship issues are not in the case. Because I rejected that argument in denying Plaintiff's motion for summary judgment as to inventorship, Plaintiff's <u>Daubert</u> motion as to this issue will also be denied.

Plaintiff further contends that Meyst's opinion on infringement should be excluded because it is improperly based on "witness statements of interested parties," referring to Meyst's reliance on "statements . . . provided to [him] from purchasers of the tearaway introducer sheaths." (Pl.'s <u>Daubert Mot. 5</u> (citing Meyst Report ¶ 130.)) Because I have not relied on Meyst's opinions on infringement in deciding the instant cross-motions for summary judgment, as to this argument Plaintiff's motion will be denied without prejudice to raise prior to trial.

Finally, Plaintiff contends that Meyst's opinion regarding the "value" of the D'839 Patent and "the potential design around to avoid infringement" should be excluded because Plaintiff is entitled to damages in the amount of Defendants' profits. (Pl.'s <u>Daubert Mot. 7.</u>) As with infringement, I have not relied on Meyst's opinions as to damages in deciding the instant crossmotions for summary judgment. Accordingly, as to this argument, Plaintiff's <u>Daubert motion</u> will be denied without prejudice to raise prior to trial.

2. Gerald Mossinghoff & Dana Trexler Smith

Mossinghoff, a patent attorney and former PTO commissioner, provides opinions on inventorship, indefiniteness, and inequitable conduct. Smith, a forensic accountant, provides opinions on damages. Because I have not relied on these experts' opinions in deciding the instant cross-motions for summary judgment, Plaintiff's <u>Daubert</u> motion as to these experts will be denied without prejudice to raise prior to trial.

C. Defendants' Motion

Defendants seek to exclude the testimony of Peter Bressler, an industrial designer who offers opinions on obviousness and infringement. Defendants argue that Bressler's testimony as to infringement should be excluded because he "failed to consider all the ornamental features of all figures of the design patent, which is contrary to the Court's claim construction ruling." (Defs.' <u>Daubert Mot. 1.</u>) Because I have not relied on Bressler's opinion on infringement in deciding the instant cross-motions for summary judgment, Defendants' <u>Daubert motion</u> will be denied without prejudice to raise prior to trial.

V. <u>CONCLUSION</u>

For the reasons discussed above, Plaintiff's motion for summary judgment will be granted in part and denied in part. Specifically, Plaintiff's motion will be granted as to the invalidity defenses of indefiniteness, the on-sale bar, prosecution history estoppel, and patent misuse. In all other respects, Plaintiff's motion will be denied.

Defendants' motion for summary judgment will be denied in its entirety.

And both Plaintiff's and Defendants' <u>Daubert</u> motions will be denied—in part with prejudice, and in part without prejudice, as set out above.

An appropriate Order follows.